

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Evaluation of patient reported outcome measurements as a reliable tool to measure acceptability of the taste of paediatric medicines in an inpatient paediatric population
<b>AUTHORS</b>	Mistry, Punam; Stirling, Heather; Callens, Claire; Hodson, James; Batchelor, Hannah

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Michael Rieder Department of Paediatrics, Children's Hospital of Western Ontario, University of Western Ontario, London, Ontario, Canada
<b>REVIEW RETURNED</b>	06-Mar-2018

<b>GENERAL COMMENTS</b>	<p>This is a first-of-kind study in that the authors compare various methods of taste/palatability assessment for medicines for children. Given the paucity of studies in this area in general this is a valuable study in that it provides at least a direction of what should be 'best practice' in studies of the under-appreciated but very important question of medicines acceptability for children.</p> <p>The authors have chosen to compare the various instruments available and have also compared with direct observation, an excellent concept. The statistics chosen are appropriate for the question at hand and there is a robust number of subjects in the study. The conclusions are based on the data and are not over-stated.</p> <p>There are several questions that come to mind. As this is a convenience sample of paediatric in-patients in the Midlands, did the authors include patients who may have had developmental challenges in completing the instruments used? Were potential participants screened for this? The authors do state that no cognitive assessment was made so was this study then of "all comers"?</p> <p>As well, the authors have used children as young as age 2. It is interesting in that some investigators in this field have not extended studies this early related to the thought that numeracy might be an issue, which is somewhat supported by the data in Section 3.1 as to Completeness. That being said, it appears that a number of children in the 2 - 5 year age range did successfully complete the assessments, which given the fairly large proportion of children in this study in this age range is something that the authors might note in their discussion, i.e. that it is indeed possible to assess medicines taste in very young children.</p>
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<b>REVIEWER</b>	Helen Sammons
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	Consultant Paediatrician, North Devon District Hospital.
<b>REVIEW RETURNED</b>	11-Mar-2018

<b>GENERAL COMMENTS</b>	<p>This is an interesting study that tries to provide a standard for the reporting of taste for children's medicines. It compares 3 patient related outcomes to researcher observed methods and explores the whole age range from 2-16yrs.</p> <p>It is clearly written and flows well. It is pragmatic and has good patient numbers to back up its findings for each of the scales.</p> <p>It also provides useful clinical data for clinicians on the medicines in common use and their acceptability. This could be further explored more in the discussion as could highlighting how this works relevance could be further linked to the current medicines licensing process and PIPs (compared to what happens now).</p>
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### VERSION 1 – AUTHOR RESPONSE

Response to reviewers' comments

Manuscript ID bmjopen-2018-021961 entitled "Evaluation of patient reported outcome measurements as a reliable tool to measure acceptability of the taste of paediatric medicines"

Reviewer: 1

Reviewer Name: Michael Rieder

Institution and Country: Department of Paediatrics, Children's Hospital of Western Ontario, University of Western Ontario, London, Ontario, Canada

Please state any competing interests or state 'None declared': Our group was the group that created the first facial hedonic scale for palatability measurement and we are cited in the manuscript several times. That being said I do not think this impacts on my ability to provide an unbiased and critical review

Please leave your comments for the authors below:

This is a first-of-kind study in that the authors compare various methods of taste/palatability assessment for medicines for children. Given the paucity of studies in this area in general this is a valuable study in that it provides at least a direction of what should be 'best practice' in studies of the under-appreciated but very important question of medicines acceptability for children.

The authors have chosen to compare the various instruments available and have also compared with direct observation, an excellent concept. The statistics chosen are appropriate for the question at hand and there is a robust number of subjects in the study. The conclusions are based on the data and are not over-stated.

We thank the reviewer for their positive comments on this paper

There are several questions that come to mind. As this is a convenience sample of paediatric in-patients in the Midlands, did the authors include patients who may have had developmental challenges in completing the instruments used? Were potential participants screened for this? The authors do state that no cognitive assessment was made so was this study then of "all comers"?

This was a convenience sample and we did not screen for cognitive assessment. We have answered this comment by including a statement within the manuscript to address both the convenience sampling and the cognitive function of those included.

As well, the authors have used children as young as age 2. It is interesting in that some investigators in this field have not extended studies this early related to the thought that numeracy might be an issue, which is somewhat supported by the data in Section 3.1 as to Completeness. That being said, it appears that a number of children in the 2 - 5 year age range did successfully complete the assessments, which given the fairly large proportion of children in this study in this age range is something that the authors might note in their discussion, i.e. that it is indeed possible to assess medicines taste in very young children.

We thank the reviewer for their positive comments and we have included a statement within the discussion to answer this comment. We also added to a statement in "What this study adds" to further strengthen this finding

Reviewer: 2

Reviewer Name: Helen Sammons

Institution and Country: Consultant Paediatrician, North Devon District Hospital, UK.

Please state any competing interests or state 'None declared': No competing interest

Please leave your comments for the authors below:

This is an interesting study that tries to provide a standard for the reporting of taste for children's medicines. It compares 3 patient related outcomes to researcher observed methods and explores the whole age range from 2-16yrs.

It is clearly written and flows well. It is pragmatic and has good patient numbers to back up its findings for each of the scales.

It also provides useful clinical data for clinicians on the medicines in common use and their acceptability. This could be further explored more in the discussion as could highlighting how this works relevance could be further linked to the current medicines licensing process and PIPs (compared to what happens now).

We thank the reviewer for their positive comments on this paper. We have added some text into the discussion to ensure that the impact of this work on the current medicines licensing process is explicit.

## VERSION 2 – REVIEW

<b>REVIEWER</b>	Michael Rieder Children's Hospital, London Health Sciences Centre, Western University, London, Ontario, Canada
<b>REVIEW RETURNED</b>	10-Apr-2018
<b>GENERAL COMMENTS</b>	This manuscript provides new insights into the evaluation of taste in medicines for children and as such adds new knowledge to paediatric health care providers and investigators. The authors have addressed all of the concerns raised by this reviewer.

## VERSION 2 – AUTHOR RESPONSE

\*\*\*Additional revision to provide a specific reference to Figure 1(b) has been included within the text as requested\*\*\*\*

Many thanks for the review

The manuscript has been updated with

1. An amended title to include the research question, study design and setting

2. A statement to clarify the consent/assent process for this study

A tracked changes and a plain version are available to ensure that the changes made are easily visible